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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,973	02/26/2002	James S. Norris	14017-004002 /PSU 96-1566	8113

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EXAMINER	
EPPS FORD, JANET L	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,973	NORRIS ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☒ This action is FINAL. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7,10,12,17,19-24,26,35,36 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,7,10,12,17,19-24,26,35,36 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Claims 1, 4, 5, 7, 10, 12, remain rejected and claims 19, 22-24, 26, 35-36 and 38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No.6271359. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the issued Patent recite recombinant nucleic acid comprising a nucleotide sequence encoding an autocatalytically cleaving ribozyme and one or more trans-acting ribozyme(s), operably linked to a tissue-specific or pathogen-specific promoter; recombinant nucleic acid comprising one or more ribozyme cassettes, wherein said ribozyme cassettes include pClip, pChop, and pSnip; vectors comprising said recombinant nucleic acid sequences; and virions comprising said recombinant nucleic acid, wherein said virions include a bacteriophage, and further wherein said bacteriophages include P1 and lambda phage bacteriophages.

Additionally, in regards to the ribozyme target and promoter used in the ribozyme cassettes encompassed by the issued claims, a preferred alternative embodiment of issued claims includes wherein HBV is the target and albumin is the promoter, see col. 31, lines 50-53. See also Figure 4, of the issued Patent, which describes the multiple ribozyme cassette of pChop, wherein said ribozymes are separated by at least 4 nucleotides, and wherein said cassette encodes a hairpin loop.

Thus, claims 1, 4-5, 7, 10, 12, 19 and 22-24 of the instant application are obvious variants of claims 1-2, 11-16, and 21-22 of US Patent No. 6271359.

3. Applicant's arguments filed 3-22-04 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that claims 1-7 of U.S. Patent No. 6,271,359 do not teach nor suggest a nucleotide sequence encoding an autocatalytically cleaving ribozyme comprising a first arm of complementary sequence and a second arm of complementary sequence, wherein the cleavage site of the autocatalytically cleaving ribozyme is located between the first and second arms, and wherein one of the first and second arms is proximal to the trans-acting ribozyme, and the other of the first and second arms is longer than the corresponding arm of a PCLIP cassette. Thus, According to Applicants, the presently amended claims are patentably distinct from claims 1-7 of U.S. Patent No. 6,271,359.

4. Contrary to Applicant's assertions, it is noted that claims 4-5 of the instant invention are limited to wherein the nucleotide sequence of the claimed recombinant nucleic acid molecules of the present invention are limited to wherein said nucleotide sequence encodes a pCHop cassette, and claim 5 recites wherein said nucleotide sequence encodes a pSnip cassette, and claims 3-4 of the issued patent are limited to wherein the recombinant nucleotide acid sequences comprises the pChop or the pSnip ribozyme cassette. Since the pChop and pSnip ribozyme cassettes are considered to encompass all the limitations of instant claim 1, absent evidence to the contrary, the pSnip and pChop cassettes recited in the claims of the issued patent also meet all the limitations of instant claim 1. Applicant's arguments are not persuasive.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 7, 10, 12, 17, 19-24, 26, 35-36, and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New Matter and Written Description).

Applicants have presently amended claim 1 to recite wherein the recombinant nucleic acid of the present invention comprises a nucleotide sequence that "is operably linked to a promoter with the proviso that said promoter is not a target-specific promoter that targets bacteria." As support for this amendment, Applicants refer to page 38, line 12-14, that "discloses that a promoter can target bacteria, fungi, yeast, parasites, viruses, or non-viral pathogens." According to MPEP § 2173.05(i) "Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims," if they are clearly defined in the specification as filed. In the instant case, the alternative elements referred to by Applicants, as set forth on page 38, lines 12-14, are not clearly defined since there is no clear structure associated with the target-specific promoters set forth in the specification as filed. Therefore, the current introduction of the negative limitation regarding the nucleotide sequence of the

recombinant nucleic acid sequences of the claimed invention, does not find sufficient support in the original disclosure.

Applicants have not provided a sufficient description of the claimed promoters or the trans-acting ribozymes of the current invention. Applicants have defined the claimed invention by merely reciting what the promoters do not target, by stating how the ribozymes function, and by comparing its structure with that of a pCLIP cassette.

See MPEP § 2163, which states "[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." Additionally, see the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written Description" Requirement. These guidelines state: "[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention.

In the instant case, the claiming of the recombinant nucleic acid according to the present invention merely by defining what it is not, and by providing a function of the nucleic acid is not sufficient to clearly define the invention, since there is no direct correlation between the claimed function and its corresponding structure. Although Applicants provide examples of autocatalytically cleaving ribozymes, for example pChop, PSnip, and pCLIP, the ribozymes encompassed by the instant claims are not limited to these particular ribozymes, moreover the specification as filed clearly encompasses derivatives of modified forms of these vectors, see for example page 42, line 3.

Response to Amendment

7. The Declaration filed under 37 CFR 1.132 filed 3-22-04 is sufficient to overcome the rejection of claims 1-26 and 33-38 based upon 35 USC § 102(a) as being anticipated by WO 98/24925.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

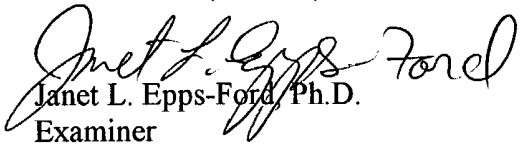
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE